



Institutional Biosafety Committee

IBC Protocol Evaluation Form

Instructions for completing the Protocol Evaluation Form

1. Complete all parts of this form.
2. All biological research investigators require IBC approval before starting. Remember that all research projects utilizing human subjects, chemicals, experimental animals or radioactive materials **MUST** obtain their approval of the IRB, Chemical Safety Committee, IACUC or Radiation Safety Committee, respectively.
3. Incomplete Protocol Evaluation Forms that do not have all the required documentations will not be evaluated until they are completed.
4. Respond to **ALL** questions in in **Section A** by checking “yes” or “no”.
5. If you answer, “yes” to **ANY** query in **Section A**, respond to **ALL** questions as directed in the applicable section(s) of the Protocol Evaluation Form.
6. Do not forget that you must submit a list of chemicals used, hazardous and otherwise, and declare their categories. Some commonly overlooked hazardous materials used in many molecular biology labs are: acrylamide monomer, ethidium bromide and formaldehyde. Please examine your methods thoroughly and report all hazardous chemicals used in the protocol.
7. Examine your protocol carefully for radioisotope use. RIA and PCR frequently involve isotope use and should be reported in **Section K**.
8. Use of PCR in a protocol requires that you check “yes” to item b and complete the applicable items in **Section E**.
9. Make sure to sign the “Acknowledgement of Responsibility and Knowledge”.

Please review the following checklist before submitting the Protocol Evaluation Form to the IBC. You should attach the required documents to this application.

- One (1) original signed copy and one (1) electronic copy submitted by e-mail
- One (1) copies of the research proposal
- Standard Operating Procedures (SOP) – If you do not have detailed SOP’S relevant to your project in the IBC’s files, please include them in this application.



Institutional Biosafety Committee

Universal Number: _____

Date Received: _____

Approval Date: _____

From: _____ to: _____

IBC Chairperson

IBC Protocol Evaluation Form

Instructions

Submit this form in conjunction with research proposals of projects dealing with:

- Infectious Agents
- Use of Human and Non-human Primates' Blood, Body fluids or Tissues
- Recombinant DNA (rDNA) Work

Investigator's Name: (Last, First, MI)

Department:

PI's Email:

Tel. Number:

Proposal/Project Title:

Funding Agency:

Proposed Start Date (mm/dd/yy):

End Date (mm/dd/yy):

Location of Work (List Building(s) and Room Number(s)):

Lab Supervisor of Key Personnel (to Answer Questions in PI's Absence):

Section A - Does the research involve the use of any of the following?

- a. **Biological Hazards** (Microbiological or viral agents, pathogens, toxins, as defined in Title 42 Code of Federal Regulations (CFR) 7.6, or animals):
Yes No
- b. **Selected Agents:** Yes No
- c. **Human or non-human cell or tissue samples** (including cultures, tissues, blood, other bodily fluids or cell lines):
Yes No
- d. **Recombinant deoxyribonucleic acid (DNA):**
Yes No
- e. **Chemicals:**
- (1) Toxic chemicals (including heavy metals):
Yes No
 - (2) Flammable, explosive, or corrosive chemicals:
Yes No
 - (3) Carcinogenic, mutagenic, or teratogenic chemicals:
Yes No
 - (4) Toxic compressed gases:
Yes No
 - (5) Acetylcholinesterase inhibitors or neurotoxins:
Yes No
- f. **Controlled Substances-usdoj.gov/dea/pubs/schedule.pdf:**
Yes No
- g. **Ionizing Radiation**
- (1) Radioactive Material:
Yes No
 - (2) Radiation generating equipment:
Yes No
- h. **Nonionizing Radiation**
- (1) Ultraviolet Light:
Yes No
 - (2) Lasers (class 3b or class 4):
Yes No
 - (3) Radiofrequency or microwave sources:
Yes No

If the answer to **ANY** of these questions is **YES**, complete all sections of the Protocol Evaluation Form that apply.

If **ALL** answers are **NO** to all of these questions, do not go any further. Sign top of form and submit to the OADRGs.

Section B

1. Write a brief overview of the project and its goals. This description needs to be understood by scientist outside your field and lay persons that are members of the committee:

2. Does your research involve the use of microbiological or viral agents, pathogens, toxins, poisons or venom?

- Yes
- No

* If **NO**, skip to the section on Cells and Tissue Samples.

* If **YES**, list all Biosafety Level 2 and 3 agents or toxins used in your laboratory.

It is the responsibility of each PI to:

A. Consult either:

- a) The National Institute of Health (NIH)-Center for Disease Control and Prevention (CDC) publication entitled Biosafety in Microbiological and Biomedical Laboratories or
- b) The CDC online reference (<http://www.cdc.gov>)

B. Identify the Biosafety Level (also called Risk Group) for each organism, agent, or toxin.

Organism, Agent, or Toxin	Biosafety Level **

*** For each Biosafety Level 2 or 3 agent or toxin listed, provide the information requested on the following page(s).*

3. Are any of the biohazardous agents listed above classified as a “Select Agent” by the Center for Disease Control?

- Yes
- No

Section D - Cells and Tissue Samples

- a. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones?

If Yes, specify:

Yes

- b. Will research studies represent a potential biohazard for lab personnel?

Yes

No

**If YES, specify the potential hazard and precautions employed to protect personnel in the laboratory:*

Note: *If these studies involve animals, it must be reported to the IACUC.*

- c. Specify precautions employed to protect personnel working in the laboratory:

Section E - Recombinant DNA

a. Are procedures involving recombinant DNA used in your laboratory?

- Yes
 No

b. Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)?

- Yes
 No

(1) If **YES**, complete **Section N** (Safety Training) and **Section O** (Procedures in Case of Accidents)

- It is your responsibility to classify your work correctly. If you are unsure whether your research is exempt or not, please do not hesitate to contact the Compliance Officer and consult the NIH Recombinant DNA Guidelines at: <http://osp.od.nih.gov/office-biotechnology-activities/biosafety>

(2) If **No**, it is the responsibility of each PI to:

(a) Consult the current *NIH Guidelines for Research Involving Recombinant DNA Molecules* which can be found at the Internet site:

<http://www4.od.nih.gov/oba/rac/guidelines.htm>

(b) Identify the experimental category of their recombinant DNA research.

c. Are detailed Standard Operating Procedures (SOP's) relevant to this project in the files of the Institutional Biosafety Committee (IBC)?

- Yes
 No

(1) If **NO**, please submit all relevant SOP's with this proposal

(3) If **YES**, does this proposal required new SOP's

- Yes
 No

(a) If new SOP's are needed, please list them below and provide copies of them in this application.

Section F – Description of Recombinant DNA Procedures:

- a. Identify the NIH classification (a brief description) for these recombinant DNA studies:

- b. Biological source of DNA insert or gene:

- c. Function of the insert or gene:

- d. Vector(s) used or to be used for cloning:

- e. Host cells and/or virus used or to be used for cloning:

Section G – Use of Non-Exempt Recombinant DNA (rDNA)

1. Provide a brief description of the non-exempt rDNA work to be conducted for this project.

2. Please provide the following information on the use of non-exempt rDNA use:

Source(s) of DNA
Name of protein(s) to be expressed (enter "none" if not applicable)

3. Is the expressed protein toxic to vertebrates? (Enter **NO** if not applicable)

- Yes
- No

4. Does recombinant contain 2/3rds of a viral genome?

- Yes
- No

5. Which of the following will serve as hosts for the rDNA? (Enter animal or plants species and population of humans if appropriate)

<input type="checkbox"/> Cultured Cells:
<input type="checkbox"/> Animals:
<input type="checkbox"/> Whole Plants:
<input type="checkbox"/> Humans:
<input type="checkbox"/> Other:

6. Describe the proposed experiments in detail. Include manipulation and analysis of materials transformed, transfected with rDNA vectors.

7. Perform a risk assessment and describe the Biohazard Potential of these experiments.

8. Address how you will mitigate the potential hazards. Indicate the required biosafety level and describe the facilities and engineering controls, the precautions (i.e. spill kit and signage) and any personal protective equipment that will be used to maintain the proper Biosafety level containment.

9. Describe the methods for the decontaminations and disposal of the waste generated from the use of the potentially hazardous materials / agents listed above. (Gloves, plasticware, materials, fluids, etc.)

http://osp.od.nih.gov/officeM_biotechnologyM_activities NIH Guidelines for Research Involving Recombinant DNA molecules (Section IB=Definition of Recombinant DNA molecules).

Section H - Use of chemicals

a. Has the use of chemicals in your laboratory been reviewed by the CSC committee or subcommittee in the past 12 months?

- Yes
- No

b. Are personnel knowledgeable about the special hazards posed by:

- (1) Carcinogens? NA YES NO
- (2) Teratogens and Mutagens? NA YES NO
- (3) Toxic gases? NA YES NO
- (4) Neurotoxins? NA YES NO
- (5) Reactive and potentially explosive compounds? NA YES NO

Section I - Controlled Substances

a. Does your research involve the use of any substance regulated by the Drug Enforcement Agency?

- Yes
- No

**If yes, list controlled substances to be used:*

- (1) _____
- (2) _____
- (3) _____
- (4) _____
- (5) _____

b. Are all Schedule II and III drugs stored in a double-locked vault?

- Yes
- No
- NA

***Note:** The schedule of controlled substances can be found at the Internet site:

<http://www.usdoj.gov/dea/pubs/schedule.pdf>

Section J - Radioactive Materials

Does your research involve the use of radioactive materials?

- Yes
- No

If **YES**, provide the following:

- a. Identify of radioactive source (s): _____
- b. Radiation Safety Committee Approval (date): _____
(mm/dd/yyyy)

Section K – Use of Infectious Agents

1. Provide the following information for all agents that you will use in this project.

Note: It is your responsibility to ensure that work with the agent is conducted in accordance with the biosafety level for which are approved to use that agent. Follow the CDC Biosafety in Microbiology and Biomedical Laboratories 5th Edition Guidelines

<http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf>

Name of Agent	Strains	Used in Vitro? Enter Biosafety Level	Used in Vivo? Enter Species and Biosafety Level

2. Describe the method of decontamination and disposal of the waste generated from the use of the agents listed above. (Gloves, plasticware, materials, fluids, etc.)

Reminder: If your project involves the use of laboratory animals, chemicals, human subjects or radioisotopes, you must also obtain approval from the Institutional Animal Care and Use Committee (IACUC), the Chemical Safety Committee (CSC), the Institutional Review Board (IRB), and the Radiation Safety Committee (RSC), respectively.

Section L - Physical Hazards

- a. Are physical hazards addressed in the facility Occupational Safety and Health Plan?
- Yes
- No
- b. Do employees receive annual training addressing physical hazards?
- Yes
- No

Section M – Use of Human or Non Human Primate’s Blood, Body Fluids or Tissues

1. Describe in the space provided below the sources of blood, body fluids or tissues, including cell lines, to be used in your project and any information relevant to determining its infectious or otherwise hazardous potential.

2. Have these materials been tested for infectious agents prior to use in your laboratory?

- Yes
- No

If **NO, describe how these infectious agents are going to be treated and their safety precautions.*

3. Describe the methods for decontamination and disposal of the waste generated from the use of the materials listed above. (Gloves, plasticware, materials, fluids, etc.)

4. Enter the names of all personnel that will be handling the human-origin material and whether they have received vaccination for Hepatitis B virus, and if that personnel have taken the required course about blood-borne pathogens. It is the policy of the Universidad Central del Caribe that all such personnel must take the required course about blood-borne pathogens. Each person that works in the laboratory is responsible for their Td vaccine and the immunization against hepatitis B virus. UCC does not provide the vaccines.

Name	Blood-Borne Pathogens Course	Td Vaccination	Hepatitis B Virus Vaccination

5. Describe how personnel have been trained in the handling of potential hazardous materials /agents to be used.

Section N – Safety Training

1. Describe how personnel have been trained in the handling of the following: rDNA, infectious agents, biological toxins, chemical toxins, human or non-human primates' blood components, body fluids and tissues, when applicable.

2. Indicate the name of the personnel that will participate in this project and their training dates. For training of personnel, courses are routinely offered by the UCC Compliance Office. Provide a copy of the certificates of the training and/or test and date taken, with this form.

Name of personnel	Training Date

Section O – Procedures in case of Accidents

1. Describe the procedures that will be performed in the event an employee, student or co-worker becomes ill, is accidentally exposed, and/or exhibits symptoms and signs consistent with exposure to any hazardous agents described in this form.

Acknowledgement of Responsibility and Knowledge

1. I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of, biohazardous materials, chemicals, radioisotopes, and physical hazards.
2. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals; radioisotopes, and physical hazards.
3. That all personnel will complete the online Biosafety Course.

_____ Date _____
Investigator's Signature

_____ Date _____
Faculty Advisor's Signature
(If investigator is a student)

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COMMITTEE MEMBER NAME	COMMITTEE MEMBER SIGNATURE	COMMENTS
Janaina Alves, PhD		
Krishna Baksi, PhD		
Henrique Martins, PhD		
Mikhail Inyushin, PhD		
Nadezhda Sabeva, PhD		
Hector Maldonado, PhD		

ACTION

Approved	_____	Approved with modifications	_____	Disapproved	_____
Chair of Biosafety Committee			Date (mm/dd/yyyy)		